REMARKS

In the Office Action dated April 10, 2007, claims 3, 8, 11 and 18 were withdrawn from further consideration by the Examiner, and claims 1, 2, 4-7, 9, 10 and 12-17 were rejected. In response, applicant submits the following comments and provides the Examiner with comparative data which discusses the cell differentiation activity of numerous vitamin D analogs in an IBD mouse model. In view of the following comments and the enclosed data, reconsideration of this application is requested.

In the Office Action claims 10, 12-16 and 17 were rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the enablement requirement. In response, applicant has canceled claims 10-18 via the present amendment. Accordingly, applicant believes this rejection is now moot and should be withdrawn by the Examiner.

In the Office Action, claims 1, 2, 4-7 and 9 were rejected under 35 U.S.C. §103(a) as being unpatentable over DeLuca et al U.S. 6,392,071 in view of Wu U.S. 5,981,597. Basically, it is the Examiner's position that it would be obvious to one of ordinary skill in the art to treat ulcerative colitis with the class of vitamin D compounds claimed because the DeLuca et al reference teaches vitamin D compounds exhibit pronounced activity in arresting the proliferation of undifferentiated cells and inducing their differentiation to the monocyte, and Wu teaches there is an increase in proliferation of cells in an undifferentiated state when one has ulcerative colitis. As a result, the Examiner believes that it would be obvious to treat ulcerative colitis with any vitamin D compound which exhibits pronounced activity in arresting the proliferation of undifferentiated cells and inducing their differentiation to the monocyte.

In addition, the Examiner rejected claims 1, 2, 6, 7 and 9 on the grounds of obviousness type double patenting as being unpatentable over claims 1, 5 and 8-11 of U.S. Patent 6,989,377. Further, claims 1, 2, 4 and 7 were provisionally rejected on the grounds of non-statutory obviousness type double patenting as being unpatentable over claim 56 of co-pending application no. 11/283,090. Also, claims 1, 2 and 4-7 were provisionally rejected on the grounds of non-statutory obviousness type double patenting as being unpatentable over claims 51-55 of co-pending application no. 11/283,291. Finally, claims 1, 2 and 4-7 were provisionally rejected on the grounds of non-statutory obviousness type double patenting as being unpatentable over claims 51-55 of co-pending application 10/235,244. Although the conflicting claims were not identical, the Examiner alleges that they are not patentably distinct. Basically, it is the Examiner's position with regard to each of these double patenting rejections that:

> "A skilled artisan would have reasonable expectation of successfully treating an inflammatory bowel disease with a vitamin D_3 compound."

The applicant respectfully disagrees with the Examiner. Applicant further believes that the following argument applies equally to the §103(a) rejection based on DeLuca et al '071 and Wu '597 as well as to all four of the double patenting rejections made by the Examiner.

As noted above, the Examiner's basic position is that one skilled in the art would have a reasonable expectation of successfully treating IBD such as ulcerative colitis with a vitamin D compound that exhibits pronounced cell differentiation activity. In response, applicant submits Exhibit 1 attached hereto which is entitled "Comparison of Vitamin D Analogs in Mouse IBD Model." The Exhibit contains nine pages and provides data comparing the efficacy against IBD of four different vitamin D compounds. The first is 1α,25-dihydroxyvitamin D_3. The second is 2-(3'-hydroxypropylidene)-19-nor-1α,25-dihydroxyvitamin D_3 (E-isomer). This second compound is designated "1AGR" in the attached Exhibit 1. The third compound tested was 2-methylene-18,19-dinor-(20S)-1α,25-dihydroxyvitamin D_3 which is designated "DP035" in the attached exhibit. The fourth compound tested was 2-methylene-1α,25-dihydroxy-(17E)-17(20)-dehydro-19-norvitamin D_3 which is designated "DP066" or "VIT-III" in the attached exhibit. As the Examiner can see from the Summary of the Results section in the exhibit, the compounds 1α,25-dihydroxyvitamin D_3 and 1AGR were effective against IBD. However, the two other compounds tested, i.e. DP035 and DP066 did not significantly reduce IBD, and were determined to be ineffective against IBD.

The significance of this data is that both DP035 and DP066 have significant cell differentiation activity. In order to support this, applicant submits a copy of U.S. published application no. 2005/0227950 A1, and refers the Examiner to paragraph 0144 contained on page 15 thereof as well as Figure 2 thereof. As the Examiner can see, the compound DP035 is stated to be "more potent" than 1α,25-dihydroxyvitamin D_3 in promoting the differentiation of leukemia cells. The Examiner should note, however, that although more potent than 1α,25-dihydroxyvitamin D_3 in cell differentiation activity, the compound DP035 is *ineffective in treating* IBD.

With regard to the compound DP066 or VIT-III, applicant submits a copy of U.S. Patent 7,241,752 B2. The applicant refers the Examiner to column 24, lines 23-26 as well as Figure 2 thereof. As stated at column 24, the compound DP066 or VIT-III has "little difference" from 1α,25-dihydroxyvitamin D_3 in its ability, i.e. both efficacy and potency, to promote HL-60 differentiation. In other words, DP066 or VIT-III is just as active in cell differentiation as 1α,25-dihydroxyvitamin D_3. The Examiner should note, however, that although just as active as 1α,25-dihydroxyvitamin D_3 in cell differentiation, the enclosed data of Exhibit 1 show that DP066 or VIT-III is not effective against IBD.

The significance of these data is that contrary to the Examiner's position, as well as what is taught in Wu '597, not all vitamin D compounds that have cell differentiation activity will treat IBD. Thus, applicant believes it would not be obvious to treat IBD with the claimed compounds despite Wu's generic statement that any compound that has cell differentiation activity would be effective against IBD. Applicant has shown that Wu's conclusion is incorrect. Thus, a combination of DeLuca et al '071 and Wu '597 does not teach or suggest, and especially does not provide a reasonable expectation of success of treating IBD with all vitamin D compounds, in view of the enclosed data. The double patenting rejections are believed also overcome since the Examiner's position that one skilled in the art would have reasonable expectation of successfully treating IBD with any vitamin D compound has been refuted in view of the enclosed data.

Accordingly, applicant requests the Examiner withdraw the §103(a) rejection as well as all four of the double patenting rejections.

An effort has been made to place this application into condition for allowance and such action has been earnestly requested.

Respectfully submitted,

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